

3.6 Electrocardiogram

Table of Contents

- I. Introduction**
- II. Background and Purpose**
- III. ECG Recording Schedule**
 - 1. Digital ECGs
 - 2. Locally Read ECGs
 - 2.1 Baseline Exclusions
 - 2.2 "Alert" ECGs
 - 3. Hospital ECGs
- IV. ECG Acquisition Procedures**
 - 1. Electrocardiograph
 - 2. System Setup
 - 3. Participant Setup
 - 4. Communication Setup
 - 5. 12-Lead Setup
 - 6. Report Sequence
 - 7. Option Code
 - 8. Supplies
- V. Recording ECGs**
 - 1. Preparation of Participant for ECG Reading
 - 2. Participant Data Entry to the MAC1200
 - 3. Electrode Lead Placement
 - 4. Chest Lead Electrode Placement and HeartSquare Instructions
 - 5. Reference Point E for Locating V4, V5 and V6
 - 6. Left Midaxillary Line
 - 7. Recording Three ECGs
 - 8. Examples of Technical Problems
- VI. Transmitting ECGs from MESA Clinics to the CERC**
- VII. Certification/Recertification Procedures**
 - 1. Certification Procedures from CERC
 - 2. Certification/Recertification Requirements to be Completed by MESA Clinics
 - 3. Recertification Procedures
- VIII. ECG Processing**
 - 1. Digital ECGs
 - 1.1 Heart Rate Variability
 - 1.2 Quality Control ECGs
 - 2. Hospital ECGs
- IX. Quality Control**
- X. Data Reporting**

CERC Personnel

Ronald J. Prineas, MD, PhD, Principal Investigator

Pentti M. Rautaharju, MD, PhD, Co-Principal Investigator

Farida Rautaharju, PhD, Center Coordinator

Margaret Mills, Administrative Assistant

Nancy (DeDe) Pemberton, .S, Systems Analyst/Data Manager

Teresa Alexander, ACS, Programmer

Jennifer Villiger, MS, BS, Statistician

Zhu-Ming Zhang, MD, Research Associate/Coding Supervisor

Ge Li, MD, Visual Coder

Yabing Li, MD, Visual Coder

Sharon Hall, Computer ECG Technician

Amy Whitman, Computer ECG Technician

Angela Bowles, Data Entry Technician II

Lisa Selph-Billings, Data Entry Technician II

Beverly Benton, Data Entry Technician II

I. INTRODUCTION

The MESA Central ECG Reading Center (CERC) is located at Wake Forest University School of Medicine, Department of Public Health Sciences, EPICARE Section. The CERC personnel are listed on the previous page. The main CERC contact numbers are:

Ron Prineas, MD., PhD, Principal Investigator

Phone: (336) 716-7441

Fax: (336) 716-0834

rprineas@wfubmc.edu

Pentti Rautaharju, MD., PhD, Co-Principal Investigator

Phone: (336) 716-0831

Fax: (336) 716-0834

prautaha@wfubmc.edu

Farida Rautaharju, PhD, Center Coordinator

Phone: (336) 716-0833

Fax: (336) 716-0834

frautaha@wfubmc.edu

Sharon Hall, ECG Technician

Phone: (336) 716-0841

Fax: (336) 716-0834

shhall@wfubmc.edu

Contact Dr. Farida Rautaharju and Ms. Sharon Hall for all matters pertaining to recording and transmission of ECGs and for ECG technician certification and recertification.

II. BACKGROUND AND PURPOSE

The ECG recordings in MESA will serve to establish the distribution of subclinical disease findings at baseline and the development of new disease (including silent myocardial infarction, left ventricular hypertrophy, ischemia, prolonged QT interval, reduced heart rate variability (HRV), and arrhythmias) as well as the development of subclinical ECG findings that are determined to be associated with a poor prognosis. Like the other non-invasive cardiovascular function measures to be employed in MESA, the ECG recordings will be used both to detect new (incident) cardiac disease and to develop predictive equations for future morbidity and mortality based on newly tested ECG findings.

This opportunity to include ECG measurements as part of MESA should take

full advantage of current technology to define subclinical ECG disease indices as well as overt ECG abnormal outcomes in the progression of disease. Just as subclinical definitions of CVD are developed for cardiac MRI, carotid ultrasound, and coronary calcium scores, different levels of subclinical disease presence will progress at variable rates in demographic subgroups, and different risk profile subgroups, and will also be associated with variable levels of subclinical CVD, as measured by alternate technologies. And, so, there are ECG findings and measurements to be incorporated into subclinical disease definitions as well as ECG risk factors to be identified. For example, MRI of the heart, with estimates of left ventricular mass (and hence degrees of left ventricular hypertrophy (LVH), may produce very different prognostic information related to obesity and elevated blood pressure than do new algorithms for ECG LVH. Therefore, the CERC will apply continuous measures of ECG LVH that predict future disease more precisely than do current dichotomous ECG LVH criteria.

Potential participants with certain manifest cardiac disease will be excluded by clinical history and examination, including ECG evidence of atrial fibrillation and the presence of a cardiac pacemaker.

III. ECG RECORDING SCHEDULE

1. Digital ECGs

- 1.1 MESA clinics will deal with three different ECG formats: (a) digitally recorded ECGs; (b) locally read baseline ECGs and “alerts,” and (c) hospital ECGs.
- 1.2 At each examination digital ECGs will be recorded electronically with a GE/Marquette MAC 1200 electrocardiograph. Each MESA site has two electrocardiographs, the software of which has been configured for correct transmission of signals by modem and phone line to the CERC.
- 1.3 The CERC will process all baseline ECGs and ECGs recorded at three scheduled follow-up examinations in MESA.
- 1.4 At each visit the clinic ECG technicians will record the scheduled ECGs with the participant *fasting*. That is, the ECG must be recorded after an overnight fast (and after this history is checked in the clinic) *and before any snack* (or at a later date the possibility of an oral glucose tolerance test) is given.
- 1.5 Each participant will have *three immediately sequential ECGs* recorded at each visit.

- 1.6 The ECGs stored in the MAC1200 will be transmitted to the CERC twice weekly (see transmission schedule below).
- 1.7 ECGs will be processed (see below) and monthly transmissions made to the MESA Coordinating Center.

2. Locally Read ECGs

2.1 Baseline Exclusions

Local reading of ECGs will be done to confirm atrial fibrillation (AF), atrial flutter, and the presence of a *pacemaker*. The presence of either of these abnormalities will be confirmed by a local clinic physician, and such potential participants will be excluded from the study and will not proceed with a carotid ultrasound, coronary calcium score, or cardiac MRI.

2.2 “Alert” ECGs

- 2.2.1 Below is a list of alerts that *do not require* immediate physician review. There are many other possible alerts that will also not require physician review, but these are the most common. It is expected that the field centers will add to this list as they gain experience with the types of alerts typically seen at their sites.

- 1st degree AV block
- Axis deviation
- Early repolarization
- Intraventricular conduction defect
- Low voltage
- Occasional PAC
- Occasional PVC
- Sinus bradycardia
- Sinus arrhythmia

- 2.2.2 Below is a list of alerts that *require immediate* physician review. Follow the specific directions given for each alert. Do not unnecessarily alarm the participant or venture a diagnosis. There are other alerts that will require immediate physician review.

- Atrial fibrillation.
- Atrial flutter.
These are not an emergency in a person without symptoms; but these ECGs should be reviewed by a physician in the clinic, and, if the ECG diagnosis is confirmed, the participant and his/her physician must be notified. The clinic physician

should also determine the urgency of advising the participant's physician and if the participant requires urgent care. Participants with atrial fibrillation are not eligible for MESA.

- Pacemaker.
No urgent or semi-urgent notification is required. This finding can simply be included in the results letter mailed to the participant and his/her physician. However, participants with pacemakers are not eligible for MESA.

- WPW
- Idioventricular rhythm
- Ventricular tachycardia
These are not an emergency in a person without symptoms; but these ECGs should be reviewed by a physician in the clinic, and, if the ECG diagnosis is confirmed, the participant and his/her physician must be notified. The clinic physician should also determine the urgency of advising the participant's physician and if the participant requires urgent care.

- Complete heart block
- Left bundle branch block
- Acute pericarditis.
- Injury, infarct, or ischemia characterized as acute or marked.
All of these are potential emergencies. The ECG should be reviewed by a physician in the clinic. If the findings are confirmed, the physician should make a judgment about whether urgent transportation for further care is required. The participant and his/her physician must be notified immediately.

- 2.2.3 If an alert is not detected by the MAC 1200, fill in the "no" bubble. If an alert is detected, and if it is reviewed and confirmed by physician review, fill in the "YES confirmed" bubble; if the alert is reviewed but not confirmed, fill in the "YES not confirmed" bubble.

2.3 Hospital ECGs **[this still needs comment from the SC]**

All MESA participant hospital admissions for suspected cardiovascular disease will be abstracted by clinic personnel, and *all hospital-recorded ECGs* for each admission should be mailed directly to the CERC with the appropriate form. A copy of *all* ECGs recorded

for each hospital event should be sent to the CERC. These ECGs will be coded by the CERC as described below in “ECG Processing.”

IV. ECG ACQUISITION PROCEDURES

1. Electrocardiograph

The electrocardiograph to be used for ECG recording and transmission for MESA is the GE/Marquette MAC 1200 portable electrocardiograph. Each clinic is provided two of these machines, all of which were formatted with the MESA SETUP at the initial training session.

- The MAC1200 is to be used for resting ECG recording and realtime ECG recording, with or without arrhythmia detection.
- It is not intended for use as a vital signs physiological monitor.
- The MAC 1200 offers no diagnostic opinion to the user. Instead, it provides analytical statements when configured, with the appropriate options.
- It is intended to be used by trained operators under direct physician supervision, when ECG records are required.
- It is designed for continuous operation.
- The MAC1200 is a portable device and can easily be moved from one location to another. However, it must be transported and handled with extreme care.
- Equipped with the standard software, the MAC 1200 supports the following operating modes:
 - 2 Lead Mode (acquisition of 12 leads of ECG for a period of 10 seconds)
 - 6 Lead Mode (real time recording of 6 ECG leads)

The MAC1200 has a liquid crystal display (LCD) that shows three leads at a time. The MAC1200s used in MESA have a customized menu specific to the MESA study. The following charts are designed to outline the SETUP for MESA, *but do not replace the MAC1200 Operations Manual provided by GE/Marquette*. A complete guide and operations manual for the MAC1200 is provided with each machine. All ECG technicians for MESA must become familiar with this manual and are urged to read the manual periodically. The manual outlines all steps for operation, loading chart paper, cleaning and disinfecting the recorder, and maintenance of the equipment. Troubleshooting and technical specifications are described in detail.

The MAC1200 has five (5) components in Setup:

- SYSTEM SETUP

- PATIENT DATA SETUP
- COMMUNICATION SETUP
- 12-LEAD SETUP
- OPTION CODE SETUP

2. System Setup

Category	Choose the following and press ENTER
ORDERING PHYSICIAN	NO
REFERRING PHYSICIAN	YES
TECHNICIAN	YES
INSTITUTION NAME	Type in your institution name (e.g., WAKE FOREST UNIVERSITY #3)
LOCATION	Type in your clinic/cart number (e.g., WAKE FOREST UNIVERSITY: 31)
CART # (= local MESA clinic #)	Type in your clinic/cart number (e.g., WAKE FOREST UNIVERSITY: 31)
SITE # (= MESA study #)	80 (This means MESA to Epicare)
LEAD FAIL BEEP	NO
HIGH HR BEEP	NO
LEAD LABELS	AAMI
DATE	MM/DD/YYYY
TIME	24 HOUR CLOCK (e.g., 3:15 p.m. = 1515)
UNITS	cm, kg
MAINS	60 HZ
LCD LIGHT OFF AFTER	5 MINS (Time out mechanism)
DEFAULT MODE	12 LEAD
LANGUAGE	ENGLISH
ENABLE PASSWORD	NO
TEST DATA	NO

3. Participant Data Setup

Category	Choose the following and press ENTER
NEW PATIENT	YES
PACEMAKER	YES (will use spikes with pacemaker)
GENDER	YES (M/F) Do not choose "-"
HEIGHT	YES (HeartSquare E measurement)
WEIGHT	YES (HeartSquare V6 measurement)
RACE	Use race codes specified in MAC 1200
SYSTOLIC BP	NO
DIASTOLIC BP	NO
ORDERING PHYSICIAN	NO
REFERRING PHYSICIAN	YES
TECHNICIAN	YES
PHONE NO.	NO
MEDICATION	NO
COMMENTS	NO
SECONDARY ID	YES
ID REQUIRED	YES (will not record without an ID)
SECONDARY ID REQUIRED	YES
LAST NAME	YES

FIRST NAME	YES
LOCATION #	YES
ROOM #	NO
ORDER NUMBER	NO
EXTRA QUESTIONS	NO

4. Communication Setup

Category	Choose the following and press ENTER
PROTOCOL	CSI
BAUD RATE (PC)	19200
MODEM	OTHER
DIAL MODE	TONE
PHONE NO.	(336) 716-1248
INITIAL MODEM	AT&FM1X3SO=1V (already entered)
OUTSIDE LINE	9-1- (or whatever number you need to get an outside line)
HANGUP	+++ATH (already entered)
DIAL STRING	ATDT (already entered)

5. 12-Lead Setup

Category	Choose the following and press ENTER
REPORT SEQUENCE	STANDARD
RHYTHM LEADS	II V1 V5
GAIN	10mm/mV
REPORT FORMAT	4X2.5R1
CONT. RHYTHM	YES
MUSCLE FILTER FREQUENCY	40 Hz
MUSCLE FILTER	NO
AC FILTER	YES
MANUAL COPY TO	EKG
NO. OF COPIES	1 (or choose 2, if needed)
DELETE ECG AFTER TRANSMISSION	NO
AUTOSAVE ECG	YES
DETAILED RESULTS	NO
OVERRIDE FUNCTION	NO
INTERPRETATION	YES
PRINT INTERPRETATION	YES
USE SCREENING CRITERIA	NO
SUPPRESS NORMAL STATEMENTS	NO
SUPPRESS ABNORMAL STATEMENTS	NO

6. Report Sequence: Standard

Channel	Lead	Label
1	I	I
2	II	II

3	III	III
4	AVR	AVR
5	AVL	AVL
6	AVF	AVF
7	V1	V1
8	V2	V2
9	V3	V3
10	V4	V4
11	V5	V5
12	V6	V6

7. Option Code

These are *preset* by GE/Marquette. Do *not* attempt to reset these codes.

Category	Code
MEAS	[335741414257]
DIAG	[761171265736]
MEMO	[SPECIFIC TO THE SERIAL NUMBER]
C100	[] , 0 0
C500	[] , 0 , 0
EVAL	[] , 0 , 0

8. Supplies

- GE/Marquette MAC1200 Electrocardiograph, 10 lead Acquisition Module
- External Modem, telephone jack cable (all part numbers for supplies are provided in the MAC1200 Operations Manual)
- MAC1200 ECG paper, GE/Marquette disposable silver chloride electrodes
- Isopropyl alcohol gauze pads and swabs
- Scissors
- Cotton surgical tape
- Felt tip non-toxic washable markers
- 1 HEARTSQUARE (directions for use in Figure 5)
- 4 strips of narrow Velcro (helpful in stabilizing the limb lead wires during recording)
- Examining table disposable paper
- 2 manuals kept within easy reach: EPICARE ECG Acquisition Procedures Manual and GE/Marquette MAC1200 Operations Manual
- Baby oil (use after ECG recording if the participant's skin appears irritated or red)

V. RECORDING ECGS

Standard 12-Lead ECGs are acquired from all study participants. ECGs are recorded after 12 hours of overnight fasting and *before* any snack or juice is

given to the participant at the clinic. *Three* routine ECGs will be recorded from each fasting participant at each exam. ECGs are recorded in a supine or semi-recumbent position. ECGs will be recorded at the following visits:

- Baseline
- Exam 2
- Exam 3
- Exam 4

All scheduled ECGs will be transmitted electronically to the MESA CERC at EPICARE.

1. Preparation of Participant for ECG Recording

- The participant's safety and comfort are of utmost importance.
- Clean sheets/examination paper must be used at all times.
- The lead placement areas must be marked with non-toxic washable markers.
- The bed must be wide enough to avoid falls. A bed that is too narrow may also result in poor quality recordings. The left arm must be properly supported. If the bed is too narrow, a portable ironing board can be attached to the left side of the bed so that the left arm may rest on it in order to keep the muscles relaxed.
- Introduce yourself. Ask the participant to relax and provide a brief explanation of the MESA study.
- Always ensure that all correct participant information is entered into your MAC1200 electrocardiograph before recording the ECG.

2. Participant Data Entry to the MAC1200

Category	Entry
NEW PATIENT	YES
LAST NAME	1 st 4 letters of last name + 1 st 2 letters of first name + gender (m or f)
FIRST NAME	SEQUENCE OF ECG: 1, 2, or 3
DATE OF BIRTH	MM/DD/YYYY
ID	Participant's ID
SECONDARY ID	Participant's ID
PACEMAKER	NO (YES, if participant has pacemaker)
GENDER	M or F
HEIGHT	E Measurement of HeartSquare (e.g., if E=16.0, enter 160)
WEIGHT	V6 Measurement of HeartSquare (e.g., if V6=12.0, enter 120)
RACE	Use other and enter defined race codes
TECHNICIAN	Use other and enter defined Tech ID #
LOCATION	Cart ID (see "System setup," Section IV.2)

3. Electrode Lead Placement

- Stand on the left side of the participant.
- Participant should be in a supine/semi-recumbent position, with chest bared. With female participants, cover the areas of the chest not used for ECG recording.
- Always follow the same procedure to ensure efficiency and quality of ECG.
- Attach a green ribbon on the Right Leg Electrode lead wire.
- Mark areas for electrode placement with non-toxic washable markers.
- Prepare the skin by rubbing areas marked (a gauze pad will abrade the skin best after using an alcohol wipe; see Figure 1, “Skin Preparation”).
- Apply electrodes on the limbs, as shown in Figure 2. Ensure that the Right Leg and Left Leg electrodes show the silver chloride end face-upwards towards the torso. The arm electrodes may face either way, depending on the height of the participant. The lead wires must show no tension or looping.

4. Chest Lead Electrode Placement and HeartSquare Instructions

- **V2**—First locate the sternal angle (Figure 3). It is approximately three-middle-fingers-width below the sternal notch. Locate **V2** at the 4th intercostal space on the left of the sternal border. Mark an “X” in the middle of the sternum at the 4th intercostal space. This will serve as a reference for **V1** and **V2**.
- **V1**—Locate **V1** at the right of the sternal border at the 4th intercostal space (Figure 4).
- **HeartSquare**—Figure 5 includes the instructions for use of the HeartSquare. The HeartSquare is used for the exact standardized location of **V4** and **V6** measurements.
- **V3 and V5**—After using the HeartSquare, you can then locate the **V3** and **V5** locations.

5. Reference Point E for Locating V4, V5 and V6

From the **V2** location, keep the middle finger of your right hand firmly in the 4th intercostal space. Then, move it down and slightly laterally until you feel the 5th rib. Immediately below the 5th rib is the 5th intercostal space. **At this level, mark an X at reference point E at the midsternal line, about 1 inch below V1 and V2.** Refer again to Figures 3 and 4.

Point E is your reference level for locating V4, V5, and V6 using the HeartSquare (Figure 5).

6. Left Mid-axillary Line

The left elbow must be supported properly. Move the left elbow laterally, without moving it anteriorly or posteriorly, while observing the anterior and posterior axillary folds. Follow a line exactly in the vertical midplane of the thorax down, where the line meets the horizontal plane of Point **E**. Using your marker, make a vertical one-inch-long line there as an approximate location of **V6**.

- Using your HeartSquare (Figure 5), find the exact location of **V6**.
- Place the HeartSquare with the wider arm horizontally at level **E**.
- Slide the thin ruler and point the arrow to the vertical line you made. This is the **V6** position.
- Mark the exact location of **V6**, where the sliding arm crosses the vertical mark you made on the midaxillary line.
- Observe and later record the **V6** reading (distance from **V6** arrow to the intersection of the horizontal ruler of the HeartSquare)
- Observe and later record the **E** reading (e.g., 16.0) as shown in Figure 5. On the vertical scale (thinner ruler), follow the diagonal line with your marker towards the chest, corresponding to the **E** reading. Mark this location as **V4**. If the HeartSquare is not long enough (e.g., in large participants), you may interpolate the reading of **E** and **V6**.
- Mark **V3** exactly between **V2** and **V4**, and **V5** halfway between **V4** and **V6**.
- Enter **E** and **V6** measurements as three digits in the Height and Weight Field in the MAC1200 as well as in your ECG Log (to be finalized by CC Figure 18).
- You have now marked the electrode positions of : **V1**, **V2**, **V3**, **V4**, **V5**, and **V6**.
- Prepare the skin at each marked location and then immediately re-mark.
- Apply all chest lead electrodes at marked locations. In most cases the silver chloride end of the electrodes are facing down towards the torso; however, in few participants, this end of the electrode may face upwards.
- When placing the **V4** electrode, do *not* move the breast. Place the electrode exactly at the position indicated using the HeartSquare. If the **V4** mark is on the nipple, place the electrode just below the nipple/areola.
- You now have all electrodes in place.
- Connect lead wires to the corresponding electrodes. Attach the limb lead wires first, beginning with the Right Leg. Attach the lead wires to Acquisition Module of the MAC 1200.
- You are now ready to enter the participant data into the MAC 1200 (see Section 2, above, "Participant data entry to the MAC 1200").

- Ask the participant to relax, breathe normally, and remain still.
- Re-check all participant data entries.
- Record the ECG, using the guidelines in the GE/Marquette MAC1200 Operations Manual.

7. Recording Three ECGs

7.1 For baseline or scheduled ECG:

- Enter all relevant information as shown in Section 2, above, “Participant data entry to the MAC 1200”
- MAC1200 prompt: NEW PATIENT: Enter **YES**
- First Name Field: Enter **1** (baseline)

7.2 Second ECG:

- MAC1200 prompt: NEW PATIENT: Enter **YES**
- First Name Field: Enter **2** (2nd ECG)
- All other information remains the same; ECG may now be recorded

7.3 Third ECG:

- MAC1200 prompt: NEW PATIENT: Enter **YES**
- First Name Field: Enter **3** (3rd ECG)
- All other information remains the same; ECG may now be recorded

Use the First Name Field to denote the sequence of the ECG. For repeat or unscheduled ECGs, enter the word “repeat” or “unscheduled.” Inspect the record immediately for quality. Repeat the recording if you spot any quality problems.

8. Examples of Technical Problems with ECG Recordings (Refer to Figures 6a–g.)

- 6a Excessive Baseline Drift** occurs if the participant is moving around or there is tension on the lead wires. Ask the participant to lie still for a few seconds. Drift in excess of 1 mm between baseline points (QRS onset) of any two successive complexes is a sign of excessive drift.
- 6b Excessive Muscle Noise/Electrodes Falling Off** can occur when the participant is tense and/or cold. Use a blanket to cover the participant. Check the Acquisition Module to ensure that the wires are not pulling. Be sure to establish a good electrode connection. Lay a towel across the wires, if necessary. Adjusting the angle of the clip at the electrode often helps. You may need to tape down the chest leads (use only hypoallergenic medical tape to prevent allergic reactions). Use a U loop with the electrode wires, i.e., the wire should not cross but remain open like a U; never loop the wires.
- 6c Motion Artifacts** indicate loose electrodes. This may cause sudden jumps in some ECG leads. Check each electrode to ensure that it is

secure. Periodic 60 HZ noise is sometimes visible in the record. This may be caused by poor electrode contact, faulty grounding, or AC interference from a nearby machine. Make a visual check of this before recording the ECG. *Note:* Jewelry does not cause 60 HZ noise.

- 6d RA/RL Reversal.** This ECG shows Lead II is flat. Check each ECG before disconnecting the participant. Check the Limb Lead connections.
- 6e RA/LA Lead Reversal.** P,Q,R,S,T are portrayed upside-down.
- 6f Suspect V1/V3 or V2/V3 Lead Reversal.** The positive QRS deflection in V3 is smaller than in V1 or V2.
- 6g Correct Sequence from V1–V6.** This is an example of an ECG with the correct connections to each electrode location.

VI. TRANSMITTING ECGS FROM MESA CLINICS TO THE CERC

- Check your Communication SETUP (see Section IV.4, “Communication Setup”).
- Telephone number: (336) 716-1248.
- If you do not have an authorization number to get an outside line, you must have a dedicated line installed. Fax lines work well.
- Visually check all ECGs on LCD to ensure correct participant information.
- Press SHIFT; Store/Retrieve (the menu has an option to Delete/Change/Send)
- Press SEND (you will have the option to send one ECG or all of the ECGs on your LCD)
- *Do NOT delete ECGs until you have confirmation of receipt of ECGs from the CERC.*

If you have problems, please refer first to your MAC1200 Operations Manual for more detailed instructions for transmitting before contacting the CERC at EPICARE.

VII. CERTIFICATION/RECERTIFICATION PROCEDURES

1. Certification Procedures from CERC

Each technician must record five (5) good quality ECGs, with the following specifications:

Last Name: Technician’s Last Name
 First Name: Technician’s First Name
 ID: 999999999
 Location: Correct Cart ID (refer to the table below)

Site	1 st MAC 1200	2 nd MAC 1200
Wake Forest	31	32
Columbia	41	42
Johns Hopkins	51	52

Minnesota	61	62
Northwestern	71	72
Loyola	73	74
UCLA	81	82

Referred by: MESA/ Certification

A certificate will be issued with the name as entered on the Certification ECGs. All ECG technicians must go through the certification process before they are allowed to record study ECGs.

2. Certification Requirements to be Completed by MESA Clinics

See Figures 8 and 9.

3. Recertification Procedures

Recertification will be required every two years and will follow exactly the certification requirements set out in Section VII.1, "Certification Procedures from CERC."

SUMMARY OF ECG ACQUISITION AND TRANSMISSION

- Call the CERC with questions regarding ECG recording procedures. Leave a detailed message with your name, study name, telephone number, and the ID in question.
- Always keep a record of the ECGs transmitted to the CERC in your ECG Log.
- Always observe the Liquid Crystal Display (LCD) and check technical quality/lead reversals before recording the ECG.
- Observe ECG on the LCD until a good quality, clean signal appears before collecting the data (i.e., before pressing 12-lead).
- Delete all duplicate ECGs (This does not mean first, second, or third ECGs required for MESA, but, rather, additional ECGs recorded because of poor quality).
- Check ECG participant data on the LCD to ensure that correct information is entered. Change/correct all incorrect information.
- Identify test and certification ECGs with ID #999999999.
- Transmit ECGs to the CERC.
- Initial and date all corrections that are faxed to CERC after transmission.
- Check SETUP every morning.
- Ensure that the correct site (= study) number (80) is entered for MESA.

- Read the GE/Marquette Operations Manuals for your MAC1200 and the modem.
- After recording ECG, clean residual paste from electrode area.
- Use baby oil (*only after*) recording ECG, if skin appears irritated or red.
- *Use extreme caution in helping the participant off the bed or table.*
- Delete recorded and stored ECGs *only* when confirmation is received from the CERC.
- The MAC1200 stores up to 35 ECGs; *however, you should transmit ECGs every day.*
- MESA clinics will be assigned specific times of the day for transmitting ECGs to EPICARE.
- Clean the ECG area and the HeartSquare with a damp cloth.
- *Replenish supplies before they are depleted!*

VIII. ECG PROCESSING

1. Digital ECGs

All MESA scheduled electronically transmitted ECGs (three per participant per scheduled visit) will be received at the CERC by a GE/Research Workstation MAC5000 machine. MESA clinics will be scheduled to make twice-weekly transmissions to the CERC. It is imperative that ECGs stored in clinic MAC1200 electrocardiographs *not* be erased until confirmation (by telephone, fax or email) of receipt by the CERC is communicated to the clinic.

The digital ECGs are stored in an electronic database at the MESA CERC, in a Marquette measurement matrix, by participant ID. This database will remain unaltered for the duration of the study. Additionally, a second and third database will be created after technician editing of correct onset and offset of QT (Measurement Editing Module (RSW) in Figure 10). These two databases are then transformed into Minnesota Code and Novacode categories by the EPICARE ECG coding program. These codes will be transmitted to the MESA CC (Figure 10). Continuous measurements of wave durations and QT interval can be used by the CC to test for trends in editing. Hardcopy of all ECGs received by the MAC5000 are also scanned by a CERC electrocardiographer for arrhythmia confirmation.

The MESA Morbidity and Mortality Committee will define ECG cardiovascular event codes. MI classification by Novacode and Minnesota Code for prevalent and incident codes follow.

Novacode Hierarchy and Criteria for Prevalent Myocardial Infarction/Ischemia (Code 5) Stratified According to Likelihood of Q Wave Infarction and Ischemic Injury and Risk of Coronary Heart Disease Mortality by the History of Heart Attack (from Rautaharju PM, Park LP, Chaitman BR et al*)

Code	Category	Criteria	Likelihood of MI/Ischemic Injury and Risk of CHD Mortality	
			History of Heart Attack	No History of Heart Attack
5.1	Q wave MI; major Q waves	Q score ≥ 35 in any lead	High	High
5.2	Q wave MI; moderate Q waves with ST-T abnormalities	Q score ≥ 25 in any lead and SID or TN score ≥ 20 in any lead group	High	Moderate
5.3	Possible Q wave MI; moderate Q waves without ST-T abnormalities	Q score ≥ 25 in any lead and SID and TN score < 20 in all lead groups	Moderate	Marginal
5.4	Possible Q wave MI; minor Q waves with ST-T abnormalities	Q score ≥ 15 in any lead and SID or TN score ≥ 20 in any lead group	Moderate	Marginal
5.5	Isolated ST abnormalities	SID score ≥ 20 in any lead group and Q score < 15 in all leads and code 6.0 (no LVH)	Moderate	Moderate
5.6	Isolated T wave abnormalities	TN score ≥ 20 in any lead group and Q score < 15 in all leads and code 6.0 (no LVH)	Moderate	Marginal
5.7	Minor Q waves	Q score ≥ 15 in any lead and SID and TN score < 20 in all lead groups	Moderate	Marginal
5.8	Minor ST-T abnormalities	SID or TN score ≥ 10 in any lead group	Marginal	Low
5.0	No significant Q waves or ST-T	Q score < 15 and SID and TN scores < 10	Low	Low

MI, myocardial infarction; CHD, coronary heart disease; SID, ST-segment depression; TN, T wave negativity; LVH, left ventricular hypertrophy.

*Rautaharju PM, Park LP, Chaitman BR, Rautaharju F, Zhang ZM. The Novacode criteria for classification of ECG abnormalities and their clinically significant progression and regression. *Journal of Electrocardiology* 1998;31(3):157-187.

Novacode Hierarchy for Classification of Incident Myocardial Infarction (MI) and Ischemia

Category	Criteria
<u>Evolving Q wave MI</u>	
I5.1 Major Q wave evolution	Q score increase ≥ 35 in one lead and ≥ 15 in an additional lead
I5.2 Moderate Q wave evolution with ≥ 15 in two leads) evolving ST-T	(Q score increase ≥ 25 in one lead or and STD or TN score increase ≥ 20)
<u>Possible evolving Q wave MI</u>	
I5.3 Moderate Q wave evolution with in two leads and nonevolving ST-T	Q score increase ≥ 25 in one lead or ≥ 15 STD and TN score increase < 20
I5.4 Borderline Q wave evolution with once STD or TN evolving ST-T	Q score increase ≥ 15 in a single lead score increase ≥ 20
<u>Ischemic ST-T evolution</u>	
I5.5 Profound ST-T evolution without increase < 15 evolving Q waves	STD or TN score increase ≥ 30 and Q score
I5.6.1. Evolving ST-T with nonevolving score ≥ 15 in ECG2 Q waves	STD or TN score increase ≥ 20 and Q and Q score increase < 15
I5.6.2 Isolated ST-T evolution score < 15 in ECG2	STD or TN score increase ≥ 20 and Q
<u>Borderline Q wave change</u>	
I5.7 Borderline Q wave evolution with and STD and TN nonevolving ST-T	Q score increase ≥ 15 in a single lead score increase < 20
<u>No significant Q or ST-T evolution</u>	
I5.0 None of the above	No codes I5.1 to I5.7

MINNESOTA CODE HIERARCHY FOR CLASSIFICATION OF INCIDENT MYOCARDIAL INFARCTION (MI) AND ISCHEMIA

Definitions of Electrocardiographic Criteria

The ECG series is assigned the highest category for which criteria are met, i.e., evolving diagnostic is greater than diagnostic is greater than evolving ST-T patterns are greater than equivocal is greater than other. The ECGs are coded using Minnesota Code.

Evolving Diagnostic (ED) ECG (Judged within lead group)

An evolving Diagnostic Q Wave pattern is defined as an evolving pattern on serial ECGs of ECG changes within lead groups, i.e., anterior (VI – V5), lateral (I, aVL, V6) or inferior (II, III, aVF). Two or more ECG recordings during the hospitalization are needed for this classification. ED1 through ED7 cannot be assigned if a 7-1-1 code is present. ED2 through ED7 cannot be assigned if a 7-2-1 or 7-4 code is present.

ED1. If the following condition is met for any lead group, then ED1 is positive. Either no Q-code or a 1-2-6 code in reference ECG followed by a record with a Diagnostic Q-code in the same lead group OR any code 1-3-x or 1-2-8 in reference ECG followed by a record with any code 1-1-x in the same lead group and there is no 7-1-1 code in either ECG, then ED1 is positive.

ED2. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG but followed by a record with a Major ST-segment Depression in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED2 is positive.

ED3. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion reference ECG but followed by a record with a Major T-wave Inversion in the same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED3 is positive.

ED4. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG but followed by a record with the ST-segment Elevation in that same lead group and there are not 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED4 is positive.

ED5. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG which is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG but followed by a record with a Major T-wave Inversion in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED5 is positive.

ED6. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG which is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG but followed by a record with a Major T-wave Inversion in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED6 is positive.

ED7. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG which is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG but followed by a record with an ST-segment Elevation in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED7 is positive.

INCIDENT MINNESOTA CODE MI (continued):Evolving ST-T (EV) Pattern (judged within lead group)

This diagnosis cannot be assigned if a 7-1-1 or 7-2-1 or 7-4 code is present.

EV1 Either 4-0 (no 4-code), 4-4 or 4-3 in reference ECG followed by a record with 4-2 or 4-1-2 or 4-1-1, OR 4-2 in reference ECG followed by a record with 4-1-2, OR 4-2, 4-1-2 or 4-1-1 in reference ECG followed by a record with 4-0, 4-4 or 4-3, OR 4-1-2 in reference ECG followed by a record with 4-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV2

Either 4-2 or 4-1-2 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-2 or 4-1-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV3

Either 5-0, 5-4 or 5-3 in reference ECG followed by a record with 5-2 or 5-1 OR 5-2 or 5-1 in reference ECG followed by a record with 5-0, 5-4 or 5-3,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV4

Code 5-2 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV5

Code 9-0 in reference ECG followed by a record with 9-2 OR 9-2 in reference ECG followed by a record with 9-0,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

1.1 Heart Rate Variability (HRV)

HRV will also be calculated from the three sequential records. For short term ECG recordings (< 20 minutes), only short term components of HRV can be calculated, and for brief recordings (as in 30 seconds for MESA) only particular time-domain measures of HRV can be calculated. It is, however, possible to derive indices from differences between normal interbeat time intervals (NN), RMSSD (see below) for an estimate of short-term components of HRV; and SDNN (see below) for an estimate of overall HRV. These are the two HRV indices that will be derived from MESA participants:

- 1.11 **SDNN** is the standard deviation of eligible NN intervals of the entire 3 records combined.

Let \bar{x} = mean of eligible NN intervals; and n = the number of eligible NN intervals; and NN_j = the j th interval; and N_j = the j th beat.

Then each eligible NN_j is obtained by subtracting QRSTIM for N_j from QRSTIM for N_{j+1} . Then SDNN =

$$\sqrt{\frac{\sum (x - NN_j)^2}{n}} \text{ msec}$$

- 1.12 **RMSSD** is the square root of the mean value of the squares of differences between all eligible successive NN intervals. Then RMSSD =

$$\sqrt{\frac{\sum (NN_{j+1} - NN_j)^2}{n - 1}}$$

1.2 Quality Control ECGs

The MESA Coordinating Center (CC) may arrange for repeated transmission of selected ECGs from the clinics to the CERC. However, because MESA participants will have three ECGs recorded at each scheduled visit, a much more powerful way of testing the repeatability of the whole ECG cascade from recording to transmission to processing and measurement can be done by comparing the ECG of record with a sample of second and third recorded ECGs (recorded for measurement of HRV).

2. Hospital ECGs

At follow-up visits MESA participants will be asked if they have had any hospital admissions since the previous visit. The MESA clinics will review all hospitalizations for possible cardiovascular disease (CVD) occurrence. For all possible CVD events copies of *all* ECGs obtained in the hospital should be labeled with participant ID information and attached to a tracking form that contains the following information:

- Date of death/morbid event
- Date of hospital admission
- Participant's age at event
- Participant's gender
- Date(s) of all hospital ECGs

The event ECGs should then be mailed to the CERC and a copy of each tracking form sent to the Coordinating Center (CC). The CERC electrocardiographers will select ECGs with maximum and minimum change for Q waves and ST-T wave segments and code for incident myocardial infarction. The maximum changes in the event ECGs will be compared to the last scheduled ECG, and serial change rules applied for both incident Novacode MI and Minnesota Code MI (see Figure 11).

IX. QUALITY CONTROL

Quality control includes certification and recertification procedures in recording. For ECG processing there are multiple editing checks and sample reprocessing done internally in the CERC at EPICARE. The quality of tracings for ECG technicians will be reported regularly to the MESA Coordinating Center (CC). Examples of ECGs with quality grades given are included below:

- Grade 1 – No artifact
- Grade 1 – Only slight muscle tremor
- Grade 3 – Some muscle tremor and some drift
- Grade 5 – Muscle tremor and drift
- Grade 5 – Poor electrode attachment
- Grade 5 – Severe muscle tremor and possible poor electrode attachment

X. DATA REPORTING

The format and route of data transfer will be determined by agreement between the Coordinating Center (CC) and the CERC. Monthly reports will be sent from the CERC to the CC. All electronic ECGs from receipt at the CERC to transmission of data to the CC will be within 30 days, and, for hospital (hardcopy, paper) ECGs, within 60 days.